

nerves, smoothing the skin, increasing blood circulation, redistributing or eliminating fatty tissue, and developing the chest and lungs.

DISPOSITION: 5-2-61. Default—destruction.

#### DRUG FOR VETERINARY USE\*

**6780. Piperazine hog and poultry wormer.** (F.D.C. No. 45790. S. No. 22-037 R.)

QUANTITY: 31 1-qt. btls. at Middlebury, Ind.

SHIPPED: 9-7-60, from Toledo, Ohio, by Miller Chemical Co.

LABEL IN PART: "Piperazine Hog & Poultry Wormer Active Ingredient: Each 100 cc Contains 17.08 grams of Piperazine Base Hexahydrate. \* \* \* Directions for use—Miller's Piperazine-A Liquid Wormer For Swine & Poultry."

LIBELED: 5-5-61, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective when used as directed in treatment for removing or controlling nodular and round worms from swine and round worms (*Ascaridia galli*) from poultry.

DISPOSITION: 6-16-61. Default—destruction.

#### INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 6741 TO 6780

##### PRODUCTS

	N.J. No.		N.J. No.
Abunda Beauty device.....	6776	Devices.....	6748, 6749, 6758, 6775-6778
Air purifier device.....	6775	Duodenal ulcers, remedy for.....	6762
All-In-One capsules.....	6764	Electronic Magnetic Model G device.....	6748, 6749
Altocaps capsules.....	6745	Equanil tablets (imitation).....	6757
Androgenic substance.....	6745	Erasurage device.....	6777
Armatinic liquid.....	6742	Family Plan Vitafood Supplement tablets.....	6774
Arthritis, remedy for. <i>See</i> Rheumatism, remedy for.		Ferbetex tablets.....	6741
Asthma, remedy for (device)....	6775	Ferrous sulfate tablets.....	6751
Barium sulfate.....	6752	Figuremaker device.....	6778
Bhaji tablets.....	6761	Hay fever, remedy for (device)....	6775
Biphetamine-T 20.....	6743	Insta-Pep tablets..... <sup>1</sup>	6746
12½.....	6743	Iro-Jex injectable.....	6744
Bursitis, remedy for. <i>See</i> Rheumatism, remedy for.		Isoproterenol hydrochloride sublingual tablets.....	6754
Bust developer (device).....	6776	Kongo-Kit massage device.....	6779
Cernelle Pollitabs.....	6771	L.G.B. 12-100.....	6755
Chick starter (medicated).....	6760	Lecitabs.....	6763
Chirata, powdered.....	6761	Lecithin tablets.....	6763
Coach-Aid Special Formula pills.....	6773	Lumbago, remedy for. <i>See</i> Rheumatism, remedy for.	
Stim-O-Stam Food Supplement tablets.....	6773	Mavene wafers.....	6762
Cosmetics (subject to the drug provisions of the Act)....	6777, 6778	Micronaire device.....	6775
Cough syrup, Olbas.....	6768	Neuralgia, remedy for. <i>See</i> Rheumatism, remedy for.	
Delamer minerals in sea water....	6766		
Deronil tablets.....	6747		

\*See also No. 6760.

<sup>1</sup> (6746) Prosecution contested. Contains memorandum and order of the court.

# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6781-6820

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., November 29, 1962.

### CONTENTS\*

	Page		Page
New drugs shipped without effective application.....	190	Drugs and devices actionable because of deviation from official or own standards....	199
Drugs in violation of prescription labeling requirements.....	192	Drugs for human use.....	199
Drugs and device actionable because of failure to bear adequate directions or warning statements.....	197	Drug for veterinary use.....	201
Drugs for human use.....	197	Drugs and devices actionable because of false and misleading claims.....	201
Drugs for veterinary use.....	198	Drug actionable because of omission of, or unsatisfactory ingredient statements.....	212
		Index.....	213

\*For failure to bear a label containing an accurate statement of the quantity of the contents. See Nos. 6786, 6794, 6820; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6783, 6784, 6786, 6801 6815, 6820; cosmetics, actionable under the drug provisions of the Act, Nos. 6815-6817.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 6781-6820

*Adulteration*, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6781. Entoquel syrup and Entoquel with Neomycin syrup (2 seizure actions).  
(F.D.C. Nos. 46217, 46220. S. Nos. 88-031/2 R, 91-339/40 R.)

QUANTITY: 20 6-oz. btls. of *Entoquel syrup* and 21 6-oz. btls. of *Entoquel with Neomycin syrup* at Baltimore, Md.; 44 6-oz. btls. of *Entoquel syrup* and 59 6-oz. btls. of *Entoquel with Neomycin syrup* at Jamaica, Queens, N.Y.

SHIPPED: Between 2-6-61 and 2-10-61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: "Entoquel Syrup (Thihexinol Methyl Bromide) \* \* \* Each Teaspoon (5 cc) contains \* \* \* Thihexinol Methyl Bromide - 5 mg. Alcohol - 1%" and "Entoquel With Neomycin Syrup \* \* \* Each Teaspoon (5 cc) contains \* \* \* Thihexinol (Entoquel) - 5 mg. Neomycin (from the sulfate) - 50 mg. Alcohol - 0.5%."

ACCOMPANYING LABELING: A promotional form letter mailed on or about 4-10-61, addressed to "Dear Doctor"; a promotional folder mailed on or about 4-27-61, entitled "Are opiates now outmoded in pediatric diarrhea?"; and a promotional folder mailed in June or July 1961, entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover.

LIBELED: 8-1-61, Dist., Md., and E. Dist, N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles was false and misleading: